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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/722,045	10/04/1996	VIRGINIA FREEMAN	P26,487-A USA	3646

7590 08/24/2004

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EXAMINER	
SPEAR, JAMES M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/722,045	FREEMAN ET AL.	
	Examiner	Art Unit	
	James M Spear	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-16 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-16 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 1996* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 5-16 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks et al US 5,354,556. Sparks et al shows a controlled release formulation comprised of microparticles wherein the particle size average diameter is 100 nanonometers or greater. See Abstract, claim 1. The particles have good uniformity in size. The controlled release microparticles comprise the same biodegradable polymers and active agents. See column 4, lines 3-5, and 59-60, column 5, lines 1-3, examples 3 and 21. The formulation is provided in effervescent forms. Column 7, lines 39-55. The skilled artisan would readily determine the requisite drug loading, release rates and ph ranges, because a controlled release composition is required. Example 1 shows preparation from an emulsion as in applicant's claim 23. Particular biodegradable polymers such as polylactides, and polyglycolides are shown in column 4, lines 3-5. Active agents such as verapamil, nifedipine, and diltiazem are shown in column 4, lines 59-60. The particles have an average size of from .1 to 125 microns. It would be reasonable for one skilled in the art to determine that when such finite particles having an average size of .1 micron are utilized the particles would be so uniform that the D 50% would be about 100 nanometers. Column 2, line 67 through column 3, line 7. The reference does not show a D 50% range between 100 nanometers and 900 nanonmeters. To use microparticles within applicants' D 50%

range with a reasonable expectation of success would have been obvious to one of ordinary skill in the art. The motivation being a desire to have uniformity in dissolution and absorption rates since particles of the same or similar size and configuration are known to provide effective release and absorption profiles. Optimum bioavailability would be obtained from particles most closely related by having the same average particle size range. See column 10, lines 3-11 and 47-68, column 14, lines 29-52. No distinction is seen in applicants' D 50 % range in the absence of a showing of unexpected results supported by scientific or clinical data.

Claims 1, 3, 5-16 and 21-29 are rejected.

Claims 2, 4, and 17-20 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

James M Spear
Primary Examiner
Art Unit 1615

August 20, 2004